K003277

DEC 21 2000

PREMARKET NOTIFICATION 510(K0 SAFETY AND EFFECTIVENESS SUMMARY

SurgASSIST™ System with Circular Stapler Disposable Loading Unit

In Accordance with 21 CFR section 807.92 PowerMed, Inc. is submitting the following safety and effectiveness summary.

1) Submitter Information:

PowerMed, Inc.
4 B East Bridge St.
New Hope, PA 18938

Contact: Michele Lucey
Prepared: October 16, 2000

2) Name of Device:

Trade Name: SurgASSIST™(Automated Steerable Surgical StaplingTechnology) Systen with Circular Stapler Disposable Loading Unit
Common Name: Circular Stapler with Implantable Staples
Classification Name: Implantable Staples

3) Predicate Devices:

CIRCULAR STAPLING INSTRUMNETS
Preamendment devices AutoSuture Reusable EEA with Disposable Cartridge
Autosuture Disposable EEA (k802611),
Ethicon ILS Circular Stapler (k920752)
3M Medical Products Group Precise Flexistapler Circular Stapler (k910897)

POWERED STAPLING AND STAPLING/CUTTING SURGICAL INSTRUMENTS
United States Surgical Powered Endoscopic GIA Stapler K(913802)

FLEXIBLE SIGMOIDOSCOPES/COLONOSCOPES/ENDOSCOPES
Pentax Precision Instrument Corporation, ES-3840, Video Sigmoidoscope (k961563)
Olympus Optical Co., LTD, EVIS EXERA Colonvideoendoscopes (k954451)

K002717

4) Device description:

The SurgASSIST™ System with Circular Stapler Disposable Loading Unit offers computer mediated steering and stapling. The system consists of the following components:

- Power Console that contains the software and electronics and drive motors.
- A steerable FlexShaft that serves as the interface between the Disposable Loading Unit and the Power Console and provides the means of insertion of the Disposable Loading Unit. The FlexShaft is steerable for positioning the Disposable Loading Unit for access and visualization.
- A hand held Remote Control Unit that contains pushbuttons that actuate steering, extension and retraction of the anvil, stapling, and cutting.
- Circular Stapler Disposable Loading Unit (DLU) that contains implantable staples that form in a double staggered circular row of staples. The Circular Disposable loading unit is offered in four sizes to accommodate a range of organ lumen.
- Storage Cart, holds Power Console, stores DLUs, Manual Over-ride and UPS.
- Manual Over-ride device to be used to manually remove the disposable loading unit.
- Optional uninterrupted power supply (UPS)

5) Indications for use

The SurgASSIST™ System with Circular Stapler Disposable Loading Unit has application throughout the alimentary tract for end-to-end, end-to-side, and side to side anastomosis.

6) Comparison to Predicate Devices

The submission for substantial equivalence included SurgASSIST™ System with Circular Staple Disposable Loading Unit literature including descriptions, specifications, identification of standard components, and identification of tissue contact materials. The submission includes a preclinical study in animals to assess the substantial equivalence of the SurgASSIST™ System against a predicate device with the same intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 21 2000

Ms. Michele Lucey
Director of Regulatory Affairs
and Quality Assurance
PowerMed, Inc.
4 B East Bridge Street
New Hope, Pennsylvania 18938

Re: K003277
Trade Name: SurgASSIST™ System with Circular Staple Disposable Loading Unit with Titanium Implantable Staple
Regulatory Class: II
Product Code: GDW
Dated: October 16, 2000
Received: October 19, 2000

Dear Ms. Lucey:

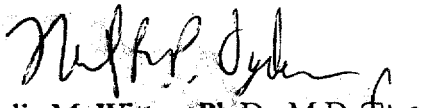
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4595. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,



Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K003277

PowerMed, Inc.
510(k)_____
October, 2000

Device Name:
SurgASSIST™ System with Circular Staple Disposable Loading Unit with Titanium Implantable Staple

INDICATIONS FOR USE:

The SurgASSIST™ System with Circular Stapler Disposable Loading Unit has application throughout the alimentary tract for end-to-end, end-to-side, and side-to-side anastomosis.

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K003277

Prescription Use X OR Over-The-Counter Use____